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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,592

Applicant(s)

BECHTOLD-PETERS ET AL.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>November 11, 2002</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 includes registered trademarks (Eudragit) as members of a Markush group. If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used to properly identify any particular material or product. MPEP 2173.05 (u). Appropriate correction or amendment is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 9, 12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Walther et al. (US 5286864). Walther teaches a tablet formulation that comprises the active agent talsaclidine, lactose, disintegrants, binders, lubricants and a

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coating (Col. 1, lines 11-57; Col. 3, lines 19-45; Col. 4, lines 3-35). Therefore, instant claims 1, 4-6, 9, 12, 14 and 16 are anticipated by the teachings of Walther.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 5-8, 10, 11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walther et al. in combination with Ni (US 4916163) or Kussendrager et al (EP 0239172 A2). The teachings of Walther are discussed above. Walther does not expressly teach that the lactose in the tablet formulations is spray-dried lactose. But does teach that the active agent can be incorporated into tablets with known pharmaceutical excipients to prepare a coated tablet. Walther also does not expressly teach the same exact concentration ranges for all the recited components of the tablet but does teach overlapping ranges.

Ni teaches a tablet formulation of an active agent that also includes spray-dried lactose as a main component (Col. 1, lines 45-68; Col. 2, lines 4-15, 26-60). The tablets of Ni also include other conventional pharmaceutical components (Col. 2, lines 4-15). The advantages taught by Ni include better bioavailability from the tablets including spray-dried lactose while the manufacture of the tablets is more convenient and economical (Col. 4, lines 10-15).

Kussendrager teaches specifically spray-dried lactose that can be included in tablet formulations. (Page 1, lines 1-6; Page 2, lines 11-15). Kussendrager teaches that the tablets produced with the spray-dried lactose are more solid tablets wherein the tablets are less subject to crushing (Page 2, lines 15-17; Page 3, lines 7-15).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare tablet formulation of talsaclidine wherein the tablet is coated and includes spray-dried lactose, disintegrants, lubricants and other conventional tableting aids.

While the reference does not teach the complete concentration ranges, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that these are limitations routinely determined by one ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some

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unusual and/or unexpected results. These results must be those that accrue from the specific limitations.

One of ordinary skill in the art would have been motivated to include spray-dried lactose to prepare a tablet that is less subject to crushing and provides better bioavailability.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walther et al. in combination with the Handbook of Pharmaceutical Excipients, 2nd Edition, 1994, pp. 362-366. The teachings of Walther are discussed above. Walther does not expressly teach that the film coating is one of those recited in instant Claim 18 or 19. Walther does teach that a coating can be included on the tablet and that the coating material can be any material known in the art as tablet coatings.

The Handbook teaches various polymers are known as film coatings for tablet formulations. Each specific polymer has its own advantages and solubility parameters that would make each suitable for specific applications. The Handbook further teaches that plasticizers can be included in the film coating composition (See the note for Table III).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare tablet formulation of talsaclidine wherein the tablet is coated with any known film coating material, especially those recited in the instant

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claims. Walther teaches any conventional tablet coating material can be used. The Handbook teaches specific conventional film coating materials.

While the reference does not teach the complete concentration ranges, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that these are limitations routinely determined by one ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. These results must be those that accrue from the specific limitations.

One of ordinary skill in the art would have been motivated to include any of the film coating materials taught by the Handbook to form a stable and safe tablet that can be used to achieve various release profiles.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
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Art Unit 1615

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